IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	Christopher T. Boyle	CUSTOMER NO.	29,335
SERIAL NO.:	09/716,146	Examiner:	C. Miller
Filed:	11/17/2000	Art Unit:	3738
Title: DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF MANUFACTURE THEREOF		Docket No:	6006-018

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SUBMISSION OF APPELLANT'S REPLY BRIEF ON APPEAL

Dear Sir:

In response to Examiner's Answer (hereinafter "Answer") mailed 10/20/2006, Appellant submits herewith Appellant's Reply Brief on Appeal, for the above-identified application. Appellant does not believe any additional fees are due in the Reply Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

APPELLANT'S REPLY BRIEF ON APPEAL

1. Status of Claims

Claims 1-15, 17-19, and 21-25 have been cancelled.

Claims 16, 20, 26-28 are finally rejected under 35 U.S.C. §102(e) as being anticipated by Brown, et al., U.S. Patent No. 6,071,305. The rejection of each claim is under appeal.

Claims 16, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Monaco et al., PCT Publication No. WO 94/18906. The rejection of each claim is under appeal.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. §102(b) as being anticipated by Yan, U.S. Patent No. 5,843,172.

Claims 16, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipate by Buirge, et al., U.S. Patent No. 5,735,897. The rejection of each claim is under appeal.

2. Grounds of Rejection to be Reviewed on Appeal

a. *Rejection of Claims 16, 20, 26-28 under 35 U.S.C. §102(e) as being anticipated by Brown, et al., U.S. Patent No. 6,071,305.*

Regarding Applicant's Claim 16, the Examiner states that Brown discloses an endoluminal stent (11, 40", 111) comprising a plurality of structural elements (element 12 seen in figure 1, however having the structure, mesh or roving wire stents, each elongated member 12 being a filament or fiber which forms a mesh stent, disclosed in col.7, lines 34-40, that is although Brown has shown a helical stent made of one structural element in Fig. 1, Brown also discloses use of a stent with multiple structural elements, wires/fibers/filaments, col. 7, lines 34-40; or element seen in cross section Fig. 12 and disclosed in col. 11, lines 50-61; or elements 112 in Fig. 18) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (col.7, lines 12-19) having a wall thickness (thickness of wire/fiber/filaments, shown in Fig. 3-12 as the cross sectional dimension), wherein the structural elements (member 12, or member shown in Fig. 12) are comprised of a base layer and a second layer covering the base layer, further comprising a void space (20) intermediate the base and second layers and enclosed therebetween.

In order to find support that Brown discloses a second layer covering the base layer with a void space intermediate the base and second layers and enclosed therebetween, the Examiner has provided drawn-on Attachments 1-5. The Examiner states that Fig. 5, attachment 1, where

one layer (marked in yellow) may be considered element 12'' and another layer (marked in red) may be considered 34, noting that although the structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only comprise metal and may include other materials as well, and the void layer 20 being therebetween.

The Examiner states that Fig. 7, in attachment 2, wherein one layer (marked in yellow) may be considered the outer perimeter of element 40, and an additional layer may be considered to be 44 (marked in green) or even 49 (marked in red), the void layer 20 therebetween. Also for Fig. 7, in attachment 3, the Examiner states that one layer (marked in yellow) may be considered the right side of outer perimeter, and a second layer (marked in green) may be on the left side of the outer perimeter (openings may exist in the layers, because the member is disclosed to be optionally made of porous metals), the void space 20 therebetween.

Then, the Examiner states that Fig. 8, in attachment 3, shows a layer to be the outer perimeter (marked in yellow) and a second layer (marked in green) and void 20 therebetween. The Examiner also states that Fig. 10 and 12 also show similar separate discrete layers.

The Examiner then states that "layer" is defined broadly by "a single thickness overlying a surface", and notes that a single thickness is not necessarily a constant thickness. The Examiner states that Brown has shown such thicknesses in all of Brown's figures, and a square cavity in a square-cross sectional element provides a single and even constant thickness. The Examiner states that Claim 16 of applicant's application do not have discrete layers, but the applicant deposits layer upon layer during the fabrication process, in order to make a unitary end product. The Examiner states that applicant's unitary end product has the same structure as disclosed in Brown.

The Examiner then states that the applicant discloses the use of other fabrication processes besides deposition to arrive at the final end product, some which do not require the use of layers. The Examiner states that while Brown may not use a deposition process to form the final structure, and may not deposit layer upon layer of material, Brown does have an end product the same as applicant's Claim 16. The Examiner quotes MPEP §2113, "Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." The Examiner states that the scope that the applicant has described "layer" in the specification, Brown also has such layers and Brown's elements may be described at a unitary structure made up of many layers. The Examiner states that one could call any particular thickness within Brown's element to be a "layer", as in Examiner's attachments 4 & 5.

Additionally, the Examiner states that Brown's elements comprise metal and are believed to read on Applicant's claims because the first and second layers are not disclosed to be made solely of metal. The Examiner also states that Brown has shown several embodiments wherein the interpreted "layers" are both metal, in attachments 2-5.

The Examiner has stated that Brown discloses a plurality of pores (pores may be openings 22, 28, 54; Col. 6, lines 12-21, or alternatively pores may be pores in the porous stent material, Col. 10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20 or channel) and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

Regarding Applicant's Claim 20, the Examiner states that Brown discloses a degradable plug residing within the plurality of pores.

Regarding Applicant's Claim 26, the Examiner states that Brown disclose a stent having structural elements comprising a material selected from the group claimed.

Regarding Applicant's Claim 27, the Examiner states that Brown discloses a bioactive agent selected from the group claimed.

Regarding Applicant's Claim 28, the Examiner states that Brown discloses a void space comprising a plurality of independent internal cavities along the length of the structural elements.

b. *Claims 16, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Monaco et al., PCT Publication No. WO 94/18906*

The Examiner has finally rejected Claims 16, 26, and 27 under 35 U.S.C. §102(b) as being anticipated by Monaco WO 94/18906. Examiner states that Monaco discloses a plurality of structural elements, with each layer may be considered a different structural element, forming a radially expandable cylinder having a wall thickness. The Examiner claims that Monaco discloses use of titanium or stainless steel, and that these two metals have been disclosed by the Applicant to be radially expandable. The Examiner also states that the Monaco discloses

elements fabricated of metal (pg. 8, lines 10-12) and comprising a base layer (housing 105) and a second layer (housing 110), further a void space (130) in-between the two and a plurality of pores (160) passing through one of the layers (both 105 and 110) and a bioactive agent (cells secreting agent or 135; pg. 7, lines 30-32; pg.21, lines 22-25) retained in the void space for release through the pores.

c. *Claims 16, 20, and 26-28 are rejected under 35 U.S.C. §102(b) as being anticipated by Yan US Patent No. 5,843,172*

The Examiner has finally rejected Claims 16, 20, and 26-29, and 27 under 35 U.S.C. §102(b) as being anticipated by Yan, U.S. Patent No. 5,843,172. Examiner states that Yan discloses an endoluminal stent (104; Fig. 1 & 9) having a wall thickness and metallic structural members comprising a base layer (middle region layer in Fig. 12; or layer 44 in Fig. 6) and second layer (outer surface region layers in Fig. 12; or layer 41 in Fig. 6), and a void space (larger pores located near the center 52) intermediate the layers and a plurality of opening (smaller pores near surface 54) connecting the cavities to the stents exterior (Col. 7, lines 1-16; Col. 8, lines 45-48), and bioactive agents (therapeutic agent) disposes with the cavities.

The Examiner also states that Yan discloses the tubular member or structural body comprising a material selected from the group claimed (Col. 4, lines 32-39); a bioactive agent or active agent selected from the group claimed (Col. 5, lines 1-30); a degradable plug (coating or matrix 100; Fig. 11 & 12; Col. 9, lines 15-40) residing within at least one of the openings.

d. *Claims 16, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Buirge, U.S. Patent No. 5,735,897*

The Examiner has finally rejected Claims 16, 26, and 27 under 35 U.S.C. §102(b) as being anticipated by Buirge, U.S. Patent No. 5,735,897. Examiner states that Buirge discloses an endoluminal stent (10; Fig. 1) having a wall thickness and metallic (discloses polymeric or other materials, Col. 2, lines 65-67, such as metals Col. 5, lines 38-46); structural elements (structural elements may be considered to be the separate layers, or the separate fibers within one layer) comprising a base layer (12) and second layer (16), and a void space (14) intermediate layers and a plurality of openings (layer 12 is porous; Col. 2, lines 53-65) connecting the cavities to the stents exterior, and bioactive agents (therapeutics/ drug; Col. 4, lines 8-27) disposed within the cavities.

3. ARGUMENT

The Examiner has proceeded during the prosecution process by a figure-by-figure examination of common elements or limitations in prior art disclosures and the filed application. It is generally known and accepted that it is the claims which define the invention, while the figures in the specification are provided for 35 USC §112 purposes. The Examiner proceeds to the deconstruct Applicant's claims into the representative figures in the filed application, and then reconstructs the prior art to conform to Applicant's figures, meanwhile ignoring the appropriate claim construction by drawing on prior art figures. In doing so, the Examiner has departed from the ordinary meaning of Applicant's claims and from one of ordinary skill in the microfabrication electronic arts. Consequently, the Examiner has resorted to a pictorial examination of the prior art and the filed application, in order to arise at a legally and factually insufficient anticipation rejection, as detailed below.

a. "Layer" is of a metal, and any other element that is not a metal does not anticipate Claim 16

The Examiner has indicated that the layers need not be made of metal at all. Answer Page 9, lines 4-5. The Examiner is misplaced in the claim construction of the "structural elements fabricated of **a metal** comprising a base layer and a second layer covering the base layer". While the Applicant has used the transitional phrase *comprising*, having the layers to be fabricated of an element that is not a metal produces something that is wholly outside the claim language of Claim 16 and the filed application. From the filed application, it can be appreciated that a clear aim and benefit of the layer disclosed in the filed application is the fabrication of the layers by **a** metal. The indefinite article "a" generally "carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising'". *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356, 55 USPQ2d 1835, 1839 (Fed. Cir. 2000). "[T]he article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article." *Id.*, 55 USPQ2d at 1839. To determine whether such circumstances exist, "'[t]he written description supplies additional context for understanding whether the claim language limits the patent scope to a single unitary [element] or extends to encompass a device with multiple [elements].'" *Id.*, 55 USPQ2d at 1839 (quoting *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1024, 43 USPQ2d 1545, 1548 (Fed. Cir.1997)).

Consequently, the claim phrase "structural elements fabricated of **a** metal" in Claim 16 indicates that the structural elements require fabrication of at least one metal, and perhaps more than one metal. However, the construction would not allow for structural elements fabricated of "a metal or a polymer". The clear intent of the applicant to limit the patent scope to single element of "a metal" is demonstrated by the following: Body element 10 is formed of **a** metal such as titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nickel titanium alloy, chromium-cobalt alloy, **or** stainless steel. Page 8, lines 23-26. Even the incorporated by reference patent application serial no. 09/443,929, which issued as U.S. Patent No. 6,379,383, discloses only forming layers by depositing a metal element. Col. 7, lines 7-67, Col. 8, lines 1-67. As such, "structural elements fabricated of a metal" is to be construed as only of one metal and not a metal and a polymer. Therefore, none of the cited prior art references anticipate the limitation of Claim 16, "structural elements fabricated of a metal comprising a base layer and a second layer covering the base layer".

i. The Examiner's Marked Up Attachments Provide no Teaching in Brown as to Layers fabricated from a Metal

Brown does not disclose structural elements having separate layers fabricated of a metal. The Examiner colors element 12'' yellow and membrane 34 red in Brown's Figure 5, to indicate a "layer covering a base layer". Attachment #1. It is noted that Claim 16 uses the transitional phrase *comprising*, which does not permit the use of additional elements that form a construct outside the claim. MPEP 2111.03. Claim 16 requires structural elements fabricated from a metal. Membrane 34 in Brown is made from a polymer, and no where in Brown does it show or teach that membrane 34 could be made from a metal. If the Claim 16's layer were to be made of a polymer, then it would unduly impose of the claim limitation of "the structural elements fabricated of a ***polymer***". So, while additional elements may be incorporated into a claim with the transitional phrase "comprising", elements themselves may not be substituted. Such a construction of Claim 16 could be envisioned by interpreting Claim 16's structural elements fabricated of "a metal" and "a polymer", or "a metal" and "a pseudometallic metal"; however, the construction cannot be structural elements fabricated of only "a polymer". The filed application sheds light on such a claim construction, as stated *supra*.

And the Examiner points to Figure 7 in Brown's disclosure as the outer perimeter of element 40 is yellow and imbibing osmotic agent 44 is green or separating member 49 is red. Again, the osmotic agent 44 is not a structural element fabricated of a metal. Contrarily, the filed application clearly describes the layer as being made from a metal: "the body element 10 is preferably formed of **a** metal such as titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, such as zirconium-titanium-tantalum alloys, nitinol, or stainless steel". Page 8, lines 23-26. Such a clear and repetitive demonstration of the layer elements being formed of a metal is shown, where there is no room for interpreting the layers to also be formed of a polymer. The Examiner has continuously ignored the clear intent to limit the invention to a singular embodiment of structural element layers being formed from a metal. More so, the Applicant has only disclosed a single embodiment for structural elements made from a metal.

And in the Examiner's attachments, the Examiner points to Figure 7 in attachment #3 where outer perimeter is in yellow and another outer perimeter is in green. An outer perimeter of structural element would not be considered to be a second layer covering a base layer, as in Claim 16. And more so, The Examiner states that opening may exist in the layers, because the member can be optionally made of ***porous metals***. Answer Page 12, lines 6-7. The Applicant has searched Brown, and nowhere could it found that structural member 12 could be made from ***porous metals***. The Examiner has misconstrued Brown's disclosure that elongated member 12 may also be formed of semipermeable or micro-porous material. Col. 7, lines 23-24. Semipermeable or microporous material is not a ***porous metal***. While Brown discusses semipermeable or micro-porous material after the disclosure that the elongated member 12 could be made from a polymer, such a disclosure is reasonably construed that the polymer may be semipermeable or micro-porous, and not the metal. Furthermore, Brown does not teach or enable a porous metal, and is counterintuitive to Brown disclosure, which teaches cavity 20 within the metal structural member 12 in order to directionally deliver an agent. If the metal structural member 12 were made from porous metals, cavity 20 would be unable to directionally deliver an agent.

And the Examiner points in attachment #3 where an outer perimeter of member 12 is colored yellow and osmotic agent 44 is green. Figure 8/attachment #3. Again, osmotic agent 44

is not a structural element fabricated of a metal as to anticipate Claim 16. Finally, the Examiner states that Figure 10 and 12 show similar separate discrete layers. Figure 10 shows a separating member made from a polymer, as to not be a metal layer. And figure 12 shows an osmotic agent, which is not a metal layer, as stated *supra*. As such, none of the Figures marked up by the Examiner nor disclosed by Brown are "structural elements fabricated of a metal comprising a base layer and a second layer covering the base layer" as to anticipate Claim 16.

b. "Layer" is a construed consistent with the specification as having inherent structural elements of deposition technologies

The Applicant has not stated that the term "layer" is defined by the specification, but rather that the term "layer", as recited in Claim 16, is to be construed consistent with the specification. During patent examination, the pending claims must be "given their broadest reasonable interpretation ***consistent with the specification***." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000), emphasis added. The Examiner does not have to assume that the term layer requires a deposition process by its meaning, because the term "layer" as used in Claim 16 inherently requires a deposition process. Claim 16 indicates a base layer and a second layer covering the base layer further comprising a void space intermediate the base and second layer. Claim 16 is enabled and supported by vacuum deposition technologies which must be modified to deposit requisite patterns of sacrificial material over a base layer, then depositing a second layer over the sacrificial material. Page 11, lines 9-12. And deposition processes were more fully described in U.S. Patent No. 6,379,383 ('383 patent), Col. 5, lines 29-31, incorporated by reference in the filed application, Page 11, lines 5-7. The '383 patent indicated that "suitable deposition methodologies...are plasma deposition and physical vapor deposition which are utilized to impart a *metal layer* onto the stent pattern". The specification thus conveys "layer" by such deposition process, as recited by Claim 16, due to the second layer covering the base layer with a void space intermediate the base and second layer.

More so, one of ordinary skill in the microelectronic arts construes layer as to be a vacuum or chemical deposited thickness of atoms. "Layer" is considered to be thickness of deposited atoms on the order of range between several microns to several hundred microns, in the microelectronic arts. And while "layer" in the general sense encompasses various structures and bodies of art—layers of abstraction in software models, a horizontal deposit or stratum in the earth's crust, or one of several items of clothing worn on top of one another—the applicant has

chosen a meaning of the term layer in specific sense, a particular backdrop as to not read upon a stratum in the earth's crust or a piece of clothing to keep warm.

Finally, a layer has inherent structural features that are direct result of the deposition process by which it is made, as recited in Claim 16. Such structural features result in different surface energies of the layer, such as grain size, grain phase, grain material composition, stent-material composition, and surface tomography. '383 patent, Col. 4, lines 43-47. Such structural features are the result of the deposition process used to create a layer. Deposition processes produce layers with different structural characteristics than bulk material conventional processes. Heterogeneities are one structural property which may be controlled by deposition processes, but nevertheless is present in deposited layers. Heterogeneities which may be controlled by deposition include the structural properties of grain size, grain phase, and surface tomography, all which are present in "layers". Grain size, grain phase, and surface tomography are not present in the wires, strands or filaments that Brown discloses, nor can they be controlled. Wires, strands, and filaments are made by conventional die casting, melting, and molding processes and are not deposited. Such conventional methods result in surface and subsurface inclusions to disrupt the regular distribution pattern of surface free energy and electrostatic charges. '383 patent, Col. 2, lines 34-37. As such, Brown's wires, strands, or filaments does not teach layers as used in Claim 16, the specification, and one of ordinary skill in the microelectronic arts.

i. The Examiner has ignored the structural limitations of a deposited layer, if "layer" is a process limitation

If "layer" were to be considered a process limitation, then the structure implied by the process step of deposition methodologies has been completely ignored by the Examiner. The Examiner states that "layer" could be considered a method of fabrication, if layer required a deposition process, which is irrelevant in a product claim. Answer Page 8, lines 15-18. Yet, the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art...where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. MPEP §2113, *see*, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). The "layer" structure implied by the deposition methodologies includes the increased atomic packing density in the deposited material during ion beam assisted evaporative deposition. Col. 5, lines 60-67, U.S.

Patent 6,379,383, incorporated by reference under U.S Patent Application Serial No. 09/443,929, Page 11, lines 5-7. The "layer" structure also implies a film structure on the order of several hundred microns. Col. 6, lines 6-8, '383 Patent. And the "layer" structure implies a crystalline structure of the deposited film with specific grain sizes, grain phases, and surface topographies allotted in the structure of a metal layer. Col. 4, lines 44-47. Consequently, the structure implied by the process steps of deposition methodologies imparts distinctive structural characteristics to the final product of Claim 16 as to render Brown inappropriate to anticipate Claim 16.

And finally, the Applicant has come forward with sufficient evidence that there are unobvious differences between the claimed product and the prior art. The applicant must come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. MPEP §2113, *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). The *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best,* 562 F.2d at 1255, 195 USPQ at 433.) The differences cited above between layer and wrought metal parts disclosed in Brown are unobviously different to one skilled in the field of implantable medical devices. Wrought metal parts do not possess the characteristics of the claimed product in Claim 16, i.e. uniformly thin films layers with complex three dimensional geometries, such as grain size, grain phase, grain material composition, and surface topography. Consequently, there are unobvious differences between the claimed product and the product disclosed by Brown, as to render the §102(b) rejection legally insufficient.

c. Alternatively, the Examiner still misconstrues the meaning of "layer" as a "single thickness of material overlying a surface", as Brown does not disclose layers of a single thickness

The Examiner has indicated that "layer" may be considered a thickness of material spread over a surface, or a piece of clothing placed on another piece of clothing. Answer Page 8, lines 20-22. Such a meaning is wholly inconsistent with the specification and one of ordinary skill in the microfabrication electronic arts. "Layer" is broadly defined as a "single thickness of some material covering a surface". American Heritage Stedman's Medical Dictionary, Houghton Mifflin Company, (2002). If a "layer" were not a single thickness, then it would not be a layer, but a "multilayer"—"Multi" meaning "more than one", and "multilayer" meaning "more than a single thickness of some material". All of the references have a thickness of some material

which more than one. Such a multilayer is clearly seen in all of the Brown figures 3, 4, 5, 6, 7, 8, 11, and 12. Most notably, the multilayer embodiments of Brown show and teach multilayers, while the Examiner even colors Figure 4 as having 7 total layers in the stent. Nowhere in Brown does a single layer covering a single base layer appear, taught, or suggested. As such, none of the cited prior art references are legally or factually sufficient to render Claim 16 anticipated.

Furthermore, the Examiner indicates that a single thickness is not necessarily a constant thickness. Answer Page 12, lines 10-12. Applicant points to a definition of "single", which is defined as "only one in number" and the definition of "thickness", which is the "dimension between two surfaces of an object, usually the dimension of smallest measure". www.dictionary.com. Therefore, a "single thickness" can be construed as only one dimension between two surfaces of an object, which is necessarily a constant thickness. If there is more than one dimension between two surfaces, i.e. different thicknesses, then it would not be a layer, but a multi-layer element. And the Examiner has indicated that layer need not be a single constant thickness, nor a planer flat thickness. The Examiner has proceeded to misinterpret Applicant's definition of "layer", by defining "layer" as a single ***constant*** and ***flat*** thickness. Such a new definition is inconsistent with the filed application and Applicant's arguments.

More so, the Examiner cites Fig. 7 as being a constant thickness and as a square cavity in a square cross sectional element. Col. 6, lines 1-5. This disclosure by Brown would not reasonably convey a "layer covering a base layer" of Claim 16. Such a square cross sectional element still would not be a layer, because it would contain a multitude of layers as to not be a single thickness. The Examiner even indicates that Brown's element may be described as made up of ***many layers***, Examiner's Answer, Page 10, lines 13-14, emphasis added. Such layers would not be a single layer, and Brown does not teach or show how a single "layer" would cover a single "base layer". And while the Examiner states that Brown has a single thickness to be layer with a square cavity in a square cross-sectional element, Answer Page 12, lines 13-15, such a square cavity could not be reasonably construed to have a "second layer covering a base layer".

And the Examiner again has misconstrued the argument that Claim 16 has discrete layers, stating that Applicant does not have discrete layers. Answer Page 12, lines 16-17. Applicant has claimed discrete layers, as being "**a** base layer and **a** second layer covering the base layer". Since "discrete" merely means "apart or detached from others", then the layers are naturally "apart or detached from each other", or more simply put, separate claim elements of Claim 16.

Such claim construction is necessary to give meaning to the "void space intermediate the base and second layers and enclosed therebetween" limitation. The layers have to be discrete, i.e. apart or detached from each, in order to have the void space intermediate and enclosed therebetween the second layer and the base layer. Consequently, the unitary end product, as recited in Claim 16, does not have the same structure as disclosed in Brown.

Finally, the Examiner has contradicted herself by indicating that Brown discloses metal layers, Fig. 7/attachment 3, where the Examiner indicates that Brown's elements may be described at a unitary structure made up of many layers. If Brown is a unitary structure made up of many layers, then Brown could not be construed as having a single "layer" covering a single "base layer" as to anticipate Claim 16. Most notably, the Figure 7 mark up by the Examiner does not disclose a second layer "covering" a base layer. The second layer marked in Figure 7 of attachment 3 is covering the fluid imbibing osmotic agent 44, which is not a metal layer. Therefore, Brown does not contain each and every element of Claim 16 and is legally insufficient to anticipate Claim 16.

d. <u>Brown fails to disclose degradable plug residing within the pores</u>

The Examiner states that the cavities 20 in Brown are filled with drugs and inherently will fill the pores as well, due to the method of production, which entails sloughing off excess drug. Answer Page 10, line 21 to Page 11, line 1. An excess portion of a drug solution cannot be construed to inherently be a degradable plug. Drugs and degradable plugs are chemically inapposite to each other, where the former has an acceptable pharmaceutical action and the latter has a biodegradable index to disintegrate in biological media. If a drug were to disintegrate in biological media, it would cease to have an acceptable pharmaceutical action and not be within the commonly accepted definition of "drug". Figures 3, 9, and 12 do not show or teach a biodegradable plug merely by having the drug extending into the pore. The drug extending into pores would elute by diffusion, and would not plug the cavity 20 as the Examiner states. If the Examiner is stating a finding of fact, then the Applicant requests that the Examiner come forward with specific evidence, as required by administrative proceedings. See MPEP §2144.03, "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known". Consequently, Brown does not show or teach a degradable plug residing within the pores.

e. Brown does not disclose independent internal cavities

With reference to Claim 28, the Examiner states that Brown discloses multiple structural elements 12, which may be configured to form a mesh stent. Answer, Page 11, Lines 5-9. The Examiner then states that each structural element 12 at least has its own independent cavity to allow the stent to have multiple structural elements and multiple cavities present. Answer, Page 11, Lines 5-9. While Brown does disclose that the helical coil shape of structural element 12 may be configured to an expandable tube stent, it does not necessarily follow that other configurations of the stent would lead to independent internal cavities. Multiple structural elements for different stent configurations, as taught by Brown, would lead to multiple structural elements whereby the internal cavity 20 would intersect at various points where the structural elements meet to form a different stent configuration. Such an intersection of two internal cavities would not lead to independent cavities, but cavities, which are directly dependent on control and constraint with each other, as to not be "independent". Therefore, Brown does not show or teach independent internal cavities because Brown reasonably conveys cavities that would not be free from control or constraint.

And the Examiner has cited to Figures 9, 10, and 18 as examples of how multiple independent cavities may be incorporated into one structural element 12. The Examiner presumes that all different features of element 12 may be combined since structural element 12 is used for all embodiments. No such teaching or enablement supports such a conclusion; merely aggregating elements is insufficient for anticipation and obviousness. If the Examiner is indicating an argument for inherent anticipation, then the Examiner must come forward with extrinsic evidence of such. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.' " MPEP 2113, *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

However, the Applicant may show that prior art products do not necessarily or inherently possess the characteristics of the claimed product, when the rejection is based on 'inherency' under 35 U.S.C. 102, by showing that the claimed product includes unobvious differences. MPEP 2113. There are unobvious differences between the independent internal cavities of Claim 28 because independent internal cavities must be "along the length of the structural elements". Contrarily, the Examiner is proposing that the cavities may not run the entire length

of the structural element 12 in Brown. More so, the Examiner points to Figure 9 as one structural element 12 with multiple cavities present. The two cavities 20 in Figure 9 are not independent because they do not exist free from control or restraint from each other. And while Brown discloses that the cavities may or may not extend the entire length of the structural element 12 in Brown, Brown does not show or teach how a cavity is to exist independently from another cavity along the length of the structural element. And Figure 18 discloses grooves 120 that extend helically around the tubular member as to not be internal cavities or independent internal cavities. Therefore, Brown does not contain each and every element of Claim 16 and is legally insufficient to anticipate Claim 16.

f. Monaco

The Examiner has inappropriately applied Monaco against the filed application. Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. MPEP 2125, *In re Mraz*, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). However, the picture must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). An artificial organ cannot anticipate an endoluminal stent, when the pictures in Monaco do not show the any stent-like structure, which is claimed in Claim 16. While the Examiner defined the stent as a tubular object only, this draws upon myriads of irrelevant prior art which merely disclose tubes. The capability of holding open a vessel in the body is the hallmark feature of stent and requires specific structural tolerances and properties in order to be qualified as a stent. To ignore an intended purpose when such purpose is paramount to structural characteristics is an oversight by the Examiner.

Moreover, the Examiner states that "a thickness does not determine whether a tube is capable of fitting within a vessel, the diameter does". Examiner's Answer Page 14, lines 15-16. Contrarily, thickness does determine whether a tube is capable of fitting within a vessel. The thickness of a tube directly correlates with the diameter of a stent, i.e. the thickness of two opposing sides of tube increase the diameter of a stent upon expansion into a vessel. If the thicknesses are larger, then the diameter of the stent will be less, as compromised upon the tolerances of the thicknesses. For this reason, it is why stents are specifically constructed to sub-micron thicknesses.

Additionally, the applicant's stent is an endoluminal stent. While endoluminal stent is in the preamble of Claim 16, it imparts specific structural limitations on the claim. Statements in

the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference between the claimed invention and the prior art. MPEP 2112.02. If so, the recitation serves to limit the claim. See, *e.g.*, *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). The endoluminal stent is required to be delivered using transcatheter approaches, so stents are delivered in a reduced diametric state and are expanded or allowed to expand in vivo to an enlarged diametric state. Page 5, lines 7-9 of filed Application. The Monaco device could operate as a stent, could not be delivered using transcatheter approaches, and is not an endoluminal stent. Therefore, "endoluminal stent" is to be given patentable weight as to be outside the scope of the Monaco disclosure.

g. Yan

The Examiner has misconstrued Applicant's argument with regard to Yan. The Examiner states that the applicant has argued that Yan does not disclose several layers of a single constant thickness. Answer Page 15, lines 5-6. Again, the applicant has not argued a constant thickness, but rather a single thickness. A single thickness is required by a layer, as a plain and ordinary meaning argued above. While the Examiner attempts to characterize Figure 12 as having layers, such layers in Yan are diameter particles and are not taught or shown to be within the scope of Claim 16.

i. Yan does not disclose a degradable plug

Yan does not teach a degradable plug, as recited in Claim 20. The Examiner indicates that Yan disclose coatings applied to a metallic stent and inherently the coating will seep into the openings, since pressure must be applied to place the coating on the stent. Answer Page 15, lines 12-14. If the Examiner is stating a finding of fact, then the Applicant requests that the Examiner come forward with specific evidence of the fact that a coating would seep into the openings in Yan. Contrarily, the Yan reference discloses the coating as a film or polymeric layer which is on the order of 0.002 inches thick, Col. 9, lines 39-40, while the openings disclosed in Yan are the on the order of 0.01-20 microns in diameter and the size of the particles are 0.02-20 microns in diameter. Such a thickness of a coating would not inherently seep into and plug a cavity with such dimensions. Yan does not teach a plug, i.e. to fill a hole tightly, but only a coating, i.e. layer of substance spread over a surface. American Heritage Dictionay, 2006. Therefore, Yan is factually and legally insufficient to anticipate Claim 20.

h. Buirge

The Examiner has misconstrued Claim 16's void space. Applicant has claimed a void space. Void is defined as "without contents, empty". www.dictionary.com. Buirge does not disclose a void space intermediate and inbetween a covering layer and base layer. Even though there may be material in Claim 16's void space, it is nevertheless void. The Examiner has misconstrued Claim 16 to fill the void space and draw unnecessary limitations into Claim 16. Accordingly, Buirge is inappropriate to anticipate Claim 16.

Summary

An anticipation rejection under 35 USC §102(e) requires that there be identity between the claimed elements and the cited prior art references. Such identity is unequivocally absent between the elements of the rejected claims and the Brown, Monaco, Buirge, and Yan references. In absence of such identity, Applicant respectfully solicits the Board to reverse the Examiner's rejections and allow Claims 16, 20, 26-28.

Respectfully submitted,

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